



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification<sup>5</sup> :</b> <b>A61M 5/20, 37/00, 5/178</b> <b>A61M 5/00</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 94/07553</b> <b>(43) International Publication Date:</b> 14 April 1994 (14.04.94)
<b>(21) International Application Number:</b> PCT/US93/09376 <b>(22) International Filing Date:</b> 30 September 1993 (30.09.93) <b>(30) Priority data:</b> 07/956,952                      5 October 1992 (05.10.92)                      US <b>(71) Applicant:</b> SENETEK PLC [GB/US]; 62A Weldon Parkway, Maryland Heights, MO 63043 (US). <b>(72) Inventor:</b> WACKS, Jonathan, L. ; 67-12 Yellowstone Boulevard, Forest Hills, NY 11375 (US). <b>(74) Agents:</b> SAMPLES, Kenneth, H. et al.; Fitch, Even, Tabin & Flannery, Room 900, 135 South LaSalle Street, Chicago, IL 60603 (US).		<b>(81) Designated States:</b> AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
<b>(54) Title:</b> MEDICAMENT INJECTORS AND METHODS		
<b>(57) Abstract</b> <p>An automatic injector/aspirator, a mechanically powered injector, medicine injection cartridges (2431) used therewith, and methods of using same to administer fluid medicaments by injection are disclosed. The injector/aspirator and injector include a chamber for receipt of the prepackaged medicine injection cartridges (2431), a rod (2440) for applying force to drive fluid medication from the cartridges (2431) through an injection needle (2423) into a subject, and a source (2013) of such driving force. The injector/aspirator includes means for controlling the rate, direction and extent of needle insertion and withdrawal, and injection or aspiration of fluid, means for data storage and programming the injector/aspirator to predetermine and vary rates according to medically relevant factors, and sensors and indicators for monitoring performance. The force to drive a mechanical injector of the invention may be provided by release of a compressed spring (2013) or gas. Locking means (2031 and 2417) are provided for preventing accidental discharge of needles (2423) or medicine from the injectors.</p>		

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NE	Niger
BE	Belgium	GN	Guinea	NL	Netherlands
BF	Burkina Faso	GR	Greece	NO	Norway
BG	Bulgaria	HU	Hungary	NZ	New Zealand
BJ	Benin	IE	Ireland	PL	Poland
BR	Brazil	IT	Italy	PT	Portugal
BY	Belarus	JP	Japan	RO	Romania
CA	Canada	KP	Democratic People's Republic of Korea	RU	Russian Federation
CF	Central African Republic	KR	Republic of Korea	SD	Sudan
CG	Congo	KZ	Kazakhstan	SE	Sweden
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovak Republic
CM	Cameroon	LJ	Luxembourg	SN	Senegal
CN	China	LV	Latvia	TD	Chad
CS	Czechoslovakia	MC	Monaco	TC	Togo
CZ	Czech Republic	MG	Madagascar	UA	Ukraine
DE	Germany	ML	Mali	US	United States of America
DK	Denmark	MN	Mongolia	UZ	Uzbekistan
ES	Spain			VN	Viet Nam
FI	Finland				

**MEDICAMENT INJECTORS AND METHODS**Background of the Invention

5       The present invention relates to injection/aspiration devices, injection devices, and to cartridge vials for use with either or both, all for medical and research purposes and more particularly to devices designed for injecting medicines and other fluids into human beings and other subjects using a hollow injection needle.

10       The invention also relates to methods of administering fluid medications by injection with a device of the invention.

15       The injection/aspiration component and some of the cartridge vial components of the invention are also configured to aspirate blood and/or other fluids. A mechanical actuator device of the invention can be adapted for use with many of the cartridges of the invention.

20       In the conventional medical procedure for injecting medicines or for aspirating blood or fluids, a syringe with a hollow injection/aspiration needle, such as a standard hypodermic needle, is used. Needles are repugnant to many patients, particularly those who must have regular injections of medicine or blood samples taken. Among these are elderly patients and people who must have daily injections of insulin or other drugs. Similarly, pediatric patients are particularly afraid of needles. Exposed or visible needles are undesirable because they create fear and apprehension in many subjects.

30       Another problem in the medical field is that of the communication of infectious diseases caused by used needles and syringes and fluids therefrom coming into contact with doctors, nurses, or other medical personnel.

Needle tips often remain exposed after aspiration of a fluid or blood from a subject, or after injection of a medicine into a subject and medical personnel are sometimes accidentally pricked with such tips. This problem is particularly acute in situations where a syringe and needle have been contaminated with particularly virulent organisms such as the AIDS virus or the hepatitis virus. The risk of puncture with a contaminated needle point is of particular concern after an injection because a finger, hand or other part of the person administering the injection is typically in close physical proximity to the needle during its removal from the subject's tissues, during replacement of a needle or the needle cover or during removal of the needle from a syringe for disposal.

There is also danger of such exposures to personnel, such as maintenance people, other than medical personnel, when a used needle and/or syringe is laid aside or discarded with a needle tip still exposed. This danger continues even when a used needle and/or syringe are placed in a disposal container. For instance, it is a routine medical procedure to use a device which cuts off the tip of an exposed needle so that it may not be re-used. However, this procedure still leaves exposed needle stubs and syringe parts which may be contaminated with infectious agents and with which persons may come into contact and be infected. Thus, it is not uncommon for discarded needle stubs to protrude through plastic garbage bags or other containers and present serious risk of a puncture wound to a person handling or otherwise coming into contact with the container. Similarly, even after used needles are removed from syringes and placed in sealed containers, the exposed syringes must also be placed in sealed containers to reduce the likelihood of infectious contact with personnel. Sanitary disposal of used needles and used syringes is an expensive and time

consuming process and entails significant risk of exposure to infectious disease vectors.

As is known in the art, many injection needles are provided with removable covers which can be removed prior to an injection and replaced onto the needle after an injection to prevent unwanted needle punctures. The act of replacement of a needle cover exposes the user to additional risk of puncture because the aperture end of conventional needle covers offers little surface area around the aperture which would shield the user from the needle.

A related problem is that of the dangers of exposing a needle to the atmosphere prior to its being used in giving an injection or withdrawing a body fluid. Not only is there danger of wounds to user personnel and patients from the exposed needle tip, but also there is the danger that the exposed needle will become contaminated by airborne or aerosol borne microbial and other contaminants and infect the patient eventually injected. This danger is particularly acute in hospitals and other medical treatment areas where strains of antibiotic-resistant microbes endemically contaminate the air and all exposed surfaces. Contact with non-sterile air is a certainty with conventional, exposed-needle, syringe technology because, in this technology, needles are routinely exposed to the air or surfaces for some discrete amount of time during use. Also, in emergency use situations such as military combat, natural disasters, or industrial accidents, the unused needle may be left exposed to such contaminants by untrained, harried or inexperienced personnel.

Yet another common problem in conventional syringe/injection technology is that relating to improperly given injections. The differences in the rate which a needle must travel during insertion into and withdrawal from the subject's tissues and the rate at which a syringe piston must be operated in order to

inject or aspirate fluid in a painless manner are substantial. The techniques of various medical personnel in using conventional syringes are varied. Techniques vary according to the position of the subject, how that  
5 portion of the subject's anatomy which is to be injected is held, and by the various individual techniques of medical personnel. This problem is particularly acute with respect to untrained or inexperienced personnel. When a needle is inserted too slowly, needless pain  
10 results. These problems are overwhelmingly due to the difficulty of operating a syringe and needle in a manner which appropriately varies the rates of needle insertion and withdrawal and the rates of fluid injection and aspiration.

15 An additional problem in the field is that of dosage management. For subjects who give themselves injections, either because they require regular doses of injected pharmaceuticals or because medical personnel are not available, it is critical to insure that dosages are  
20 correct. Diabetic subjects, particularly diabetics who suffer from the related condition of blindness, often find themselves in such situations. Other blind people are similarly in need of a product which insures that both the type of medication and its dosage are correct  
25 for their specific needs. Similarly, soldiers in the field, travelers requiring regular injectable medications, and subjects in emergency situations where self-injection is necessary often have difficulty administering the proper dosage of a given drug and often  
30 have difficulty in using a conventional syringe. Such problems are also compounded by darkness or poor lighting conditions in battlefield, power failure, and other crisis or emergency situations.

It is well known in the medical injection field that,  
35 when administering a drug or other substance intramuscularly, an attempt is made to aspirate blood or other physiological fluid after insertion of the

injection needle into a site thought to be suitable. Such an attempted aspiration is made in order to interrogate the injection site (i.e., essentially, as understood in the art the volume of tissue immediately adjacent to and in fluid communication with the open end of the needle) for the presence of blood, lymph, cerebrospinal fluid, or the like. This interrogation is made to insure that pharmaceutical substances or other fluids are not unintentionally injected inappropriately, e.g., into a blood vessel, lymph vessel or into cerebrospinal fluid. The inappropriate administration of a drug or other substance into a blood vessel, lymph vessel or cerebrospinal cavity could result in any of a number of adverse effects including nausea, unwanted toxicity, paralysis, neurological damage or even death. Moreover, the administration of pharmaceutical substances to inappropriate sites often results in attenuation or loss of the substance's desired, specific functional characteristics or activities. Thus, it is of paramount importance to insure that a needle used in administering a drug or other substance be inserted into an appropriate injection site.

For subjects injecting themselves at home, in emergency situations, or in combat, it is virtually impossible to perform the correct procedure. Similarly, personnel who are untrained in medical injection procedures but must give injections because of crisis or emergency situations are much more likely to incorrectly administer a substance, either by administering an incorrect dosage or administering by placing the needle so that its tip is positioned at an inappropriate site (e.g., so that the substance is injected directly into the blood stream rather than intramuscularly).

An example where a pharmaceutical substance must be delivered to an exact site is in the administration of certain chemotherapeutic drugs for the treatment of cancer. It is essential that chemotherapeutic drugs be

delivered to the exact target tissue. Exposure of some of these drugs to the skin or to the incorrect tissue or to the bloodstream may cause severe side effects. It is thus desirable to have a means for automatically interrogating the fluids in an injection device to insure that blood or other physiological fluids are not being inappropriately aspirated from a possible injection site into the device before drug is administered with the device.

Thus, it would also be desirable to have a device which will automatically prevent injection of pharmaceuticals at an undesirable or inappropriate injection site. In other cases, however, it might be desirable or necessary to inject a drug into, for example, the bloodstream; then the interrogation would be to assure that a physiological fluid, such as blood, is aspirated into the injection device before using it to inject the drug.

In those circumstances where aspiration and interrogation are unnecessary, it is still desirable to maintain sterility of the injection needle and medicament prior to the injection, and to automatically inject a proper dose of fluid. Mechanically powered automatic injectors are desirable in situations where motorized injectors are too susceptible to battery or electrical system failure.

Mechanically powered automatic injectors are also desirable where longterm storage would prohibit the use of or decrease the effectiveness of motorized or solenoid powered injectors or other injectors requiring electrical power. Moreover, the minimum cost of manufacture of mechanical injectors of straightforward design is an important advantage over more complex designs and over designs requiring electrical components and circuitry.

Summary and Objects of the Invention

It is an object of the present invention to provide concealment of an injection needle at all stages of use, thereby reducing the apprehension of the patient.

5 It is similarly an object of the present invention to maintain sterility of an injection needle at all stages of use by providing means whereby the needle, prior to contact with the skin of a patient for penetration therethrough, is never exposed to any  
10 potentially contaminating surfaces, aerosols or airborne particles or microbes.

It is another object of the present invention to provide an injection vial which eliminates the dangers of infection or injury resulting from accidental contact  
15 with exposed needles.

It is still another object of the present invention to provide a sanitarly disposable injection vial with a needle which, after use in an injection, retracts completely into said vial to reduce the risk of disease  
20 transmission caused by the risk of exposure to a contaminated needle or to a contaminated syringe or to parts thereof.

It is yet another object of the present invention to provide a sanitarly disposable injection vial which can  
25 be safely discarded without the need for special equipment or containers and which can be safely and sanitarly disposed of in non-hospital, rugged, or emergency environments.

It is also an object of the present invention to  
30 provide an ampule or cartridge for dispensing fluid medication which can be filled by the use of conventional pharmaceutical packaging machinery, thus avoiding the substantial expense which would be required for the development and production of non-conventional packaging  
35 methods and machinery.

It is a further object of the present invention to reduce the risk of an improperly administered injection by providing means for precisely, automatically, and programmably controlling the rate of needle insertion, the rate of needle withdrawal, the rate of medicine injection, and the rate of fluid aspiration.

It is also an object of the present invention to reduce the risk that an incorrect dosage of a fluid medicine will be administered by injection.

It is a further object of the invention to reduce the risk that an incorrect drug will be administered to a subject or be self-administered by a subject.

It is an object of the present invention to provide means for the automatic interrogation of an injection site to determine whether or not the injection needle tip is at an appropriate or desired site and in the desired target tissue.

It is a further object of the present invention to provide means for automatically scanning an injection/aspiration cartridge during operation to determine if blood or other physiological fluids have been aspirated from an actual or possible injection site into the cartridge.

It is also an object of the present invention to provide means for automatically preventing the injection of medicines or other fluids into an undesired or inappropriate tissue or site.

Furthermore, it is an object of the present invention to provide means to administer a drug to a pre-selected target tissue and avoid exposure of the drug to tissues which would be undesirably damaged by such exposure.

It is yet another object of the present invention to provide a means for giving or self-administering penile injections of drugs with a minimum of pain and apprehension on the part of the male.

It is an additional object of the invention to provide a mechanically powered injector which needs no

electrical power or circuitry and which can be stored for long periods of time.

It is a similar object of the invention to provide a mechanically powered injector which is not suitable for  
5 re-use and which is suitable for sterilization by radiation, electron beams, or gases.

In accordance with the objectives of the invention, a vial for fluid injection is provided. The injection  
10 vial is a double-ended cartridge, having a first end and a second end, the cartridge having a cylindrical bore defined by a wall extending between the first end and the second end, the bore being suitable for storing a fluid charge to be expelled therefrom. A first piston and a  
15 second piston are positioned within the bore and are slidably seated against the cylindrical wall of the bore, the first piston comprising means for reversibly engaging a plunger. The cartridge is provided with a puncturable end cap which is rigidly attached and sealed to the second end of the cartridge and which comprises a needle  
20 guide. The cartridge is also provided with a hollow injection needle having an external tip and an internal tip, the internal tip being rigidly attached to and passing through the second piston, and the external tip extending toward the end cap without protruding  
25 therefrom, and means for locking the first piston and the second piston irreversibly together when the first piston and the second piston are a predetermined distance apart. It is preferred that the puncturable end cap be made of a self-sealing material, although this is not  
30 necessary for practicing the invention.

The vial may also be provided with a readable indicator to indicate the type of medication, patient  
information, the amount of medicine to be injected and the various rates of needle insertion and withdrawal and  
35 of fluid injection and/or aspiration.

In accordance with another aspect of the invention, a programmable automatic injection/aspiration device is

provided having a housing, a chamber disposed within the housing for reversibly receiving a cartridge vial, and a cartridge vial piston operating plunger slidably disposed within the housing. Also provided are means, disposed  
5 within the housing, for propelling the plunger. Similarly, controller means for controlling the rate, direction, and extent of movement of the plunger are provided. Control is thus provided via said propelling means, and a programmable processor for directing the  
10 controller, a sensor for detecting the rate, direction, and extent of movement of the plunger, an indicator for indicating the rate, direction, and extent of movement of the plunger and for indicating the amount of fluid remaining and expelled from a fluid vial, and a sensor  
15 for detecting the presence in the vial of aspirated physiological fluids are also provided. Similarly provided are means for automatically preventing injection into an undesirable target tissue upon the detection of aspirated physiological fluid, and locking means for  
20 preventing unintentional discharge of drug from a cartridge vial disposed in the injection/aspiration device.

In accordance with the invention a cartridge vial, containing a fluid medicine charge, may be inserted into  
25 an injection/aspiration device, which may then be used to administer the medicine by injection. Finally, the cartridge vial, with completely retracted needle, may be removed and discarded, while the injection/aspiration device may be repeatedly re-used with different cartridge  
30 vials.

In accordance with other objects of the invention, a mechanically actuated cartridge vial for fluid injection is provided. The mechanically actuated cartridge vial is a cartridge, having a first end and a  
35 second end, the cartridge having a cylindrical bore which is widened at the second end of the cartridge to form a cylindrical needle housing assembly residence chamber for

-11-

reversibly receiving a needle housing assembly, and a puncturable end cap, the end cap sealing the second end of the cartridge and having a needle guide disposed therein.

5       The cartridge has an ampule disposed within it, the ampule having a bore, and the bore having a first cylindrical portion, a second cylindrical portion adjacent to and narrower than the first portion, and a  
10       third cylindrical portion adjacent to the second portion and being adjacent to and wider than the second portion, the ampule being suitable for storing a fluid charge to be expelled therefrom. The ampule is provide with a  
15       piston within the first portion of the ampule and being slidably seated in the ampule and a puncturable ampule end stopper rigidly attached to and sealing the third  
      portion of the ampule.

      A needle housing assembly is disposed in the cylindrical bore of the cartridge, the needle housing assembly comprising a housing, a hollow injection  
20       needle rigidly attached to the housing and having an internal end and an external end, the internal end of the needle extending through the needle assembly housing toward the puncturable ampule end stopper, and the  
      external end of the hollow injection needle extending  
25       toward the puncturable end cap of the cartridge without protruding therefrom; and an actuator for engaging the cartridge vial and for propelling the ampule toward the puncturable end cap and for propelling the piston within  
      the ampule toward the ampule end stopper to inject a  
30       fluid.

      The needle housing assembly disposed within the cartridge is provided with locking means for irreversibly locking the needle assembly housing to the ampule when the needle housing assembly and the ampule are a  
35       predetermined distance apart. The mechanical actuator component of the invention comprises an actuator housing, the housing having a first end and a second end, the

first end adapted for receiving the cartridge vial and the second end adapted for operating the cartridge vial and actuator.

5 A piston driver is slidably seated in the housing, the driver having a piston face for contacting the ampule piston, a transfer surface for transferring propelling force from the housing to the driver, and a trigger end for releasably engaging the second end of the actuator housing. Also provided in the actuator housing are a  
10 detent in the second firing end for releasably engaging the piston driver, a detent release in the second firing end for disengaging the piston driver from the second end, and a propulsion mechanism disposed between the transfer surface and the second end of the housing for  
15 driving the piston driver toward the puncturable end cap when the detent release is triggered.

In accordance with yet further objects of the invention, the propulsion mechanism disposed in the mechanical actuator is a spring of one or more materials  
20 from the group consisting of metals, glasses, composites and plastics. Alternatively, the propulsion mechanism can be a compressed gas, such as air, nitrogen, carbon dioxide, or the like, releasably contained in a receptacle.

25 Brief Description of the Drawings

The invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a longitudinal cross-sectional view of an injection/aspiration device showing the relative  
30 placement of the cartridge vial and other components;

Figure 2 is a longitudinal cross-sectional view of the cartridge vial constructed in accordance with a first embodiment of the invention;

Figure 3 illustrates another embodiment of the  
35 cartridge vial wherein a slidable ampule functions

-13-

similarly to the first piston of the embodiment shown in Fig. 2 and alternate means for needle retraction are provided, which ampule can be manufactured using conventional pharmaceutical packaging machinery.

5        Figure 4 illustrates an additional embodiment of the cartridge vial similar to that shown in Figure 3 but for use with injections only.

10        Figure 5 is a longitudinal cross-sectional view of a cartridge vial device for use with a mechanically powered actuator showing the relative placement of the ampule, cartridge, needle housing assembly, and other components;

15        Figure 6 is a longitudinal cross-sectional view of a spring-powered cartridge vial actuator before insertion of a cartridge vial, and showing the relative positions of the actuator housing, piston driver, spring, and firing cap assembly of a preferred embodiment of the invention;

20        Figure 7 is a magnified view of the firing cap assembly shown in Figure 6 to more clearly show the details of the invention.

25        Figure 8 is a longitudinal cross-sectional view of a cartridge vial for use with a mechanically powered actuator mated to such an actuator and showing the relative placement of major components of the vial and actuator after firing of the actuator, completion of an injection, and covering of the exposed injection needle by the actuator safety pin.

#### Detailed Description of the Preferred Embodiments

30        The injection/aspiration device, illustrated in Fig 1, comprises: a housing 201 for disposition of the various components having a chamber 219 for reversibly receiving a cartridge vial of a type as described below and in Figures 2 and 3, a d.c. motor 203, a lead screw  
35        205, a linear bearing 207 for holding a lead nut, a lead

-14-

nut 213 surrounding the lead screw, and armed/safety injector switch 209, indicating light emitting diodes 211, a plunger 215 attached to lead screw 205, a cartridge vial 217 disposed within chamber 219, an electronic control unit 221, an injector trigger button 223, a d.c. power source 225, an on/off switch 227, a cartridge/ampule position locking solenoid 229 having cartridge/ampule position locking solenoid shaft 231, aspirated fluid sensor 233, and plunger shaft rate/position/direction sensor 235.

The injection/aspiration device of the invention operates in conjunction with cartridge vials as described hereinbelow. All of the components of the device are energized by d.c. power source 225 through the operation of switch 227. D.c. motor 203 propels lead screw 205 which is attached to lead nut 213 and plunger shaft 215 which is reversibly attached to cartridge vial shaft end 216 by means of a mechanical key way provided at the end of plunger shaft 215. Linear bearing 207 is provided for smooth operation of lead screw 205 and plunger shaft 215. Lead screw nut 213 is provided as an attachment means for connecting lead screw 205 to plunger shaft 215. Electronic control unit 221 is a programmable electronic processor connected by means of wires not shown to DC motor 203 to control the rate, direction, and extent of movement of lead screw 205, plunger shaft 215 and, thereby, the rate, extent of movement, and direction of movement of cartridge vial shaft end 216. Cartridge vial shaft end 216 can be of any type configured to securely but reversibly attach to plunger shaft 215. Similarly, as described below, plunger shaft 215 can be adapted to operate other types of cartridge vials such as those designed to be used with a spear type shaft of a type known in the dental cartridge field. The electronic control unit 221 is programmed by means of a programmable read-only memory (PROM), and a programmable array logic (PAL) which, depending on the application of the device,

can be interchanged to adapt the device to the age or sex of the patient, the location parameters of the injection, (such as intramuscular, subcutaneous or intravenous) for the rate of needle withdrawal and insertion, and for the rate of medicinal charge injection. The electronic control unit also comprises electronic timers which control the overall timing and specific rates during the injection process. A set of programmed instructions are stored in a replaceable and interchangeable memory chip (not shown) in electronic control unit 221. By either interchanging memory chips or by reprogramming programmable memory chips, the various functions of the injection/aspiration device can be controllably varied. Cartridge/ampule position locking mechanism 229 is a solenoid which can be activated to lock a cartridge vial in a particular position by means of cartridge/ampule position locking solenoid shaft 231 so that blood or other fluids can be aspirated. Although a solenoid and solenoid shaft are described herein as a locking mechanism, it can be clearly seen that many other means for accomplishing the objective of the device to lock any type of cartridge vial in a particular position in the injection/aspiration device housing can be used.

Similarly, although programmable and/or interchangeable memory chips are described examples herein, it can be clearly seen that many other means for programming the stated functions could be used to accomplish the objectives of the invention.

It is also clear that although a d.c. motor and power source and electronic components are described herein as means for controlling the various rates of operation of the various components of the invention that other means such as compressed gas and valves could also be used.

Although not shown in Fig. 1, the various electronic and electrical components of the invention are connected electrical circuitry.

It should also be clear that many different means for securely connecting to and easily disengaging a cartridge vial to and from plunger shaft 215 are possible. As an example and not described as a limitation, Fig. 3 shows  
5 plunger shaft 47 of an injection/aspiration device having pointed barbed plunger shaft head 49 similar to pointed shafts known in the dental injection cartridge field which is driven a sufficient distance into piston 45 during operation of the invention that a sufficiently  
10 secure connection is made to operate piston 45 in both directions. Disconnection of barbed head 49 from piston 45 is achieved by the retraction of plunger shaft 47 and plunger shaft head 49 a sufficient distance into lead nut 213 which is of an appropriate internal diameter to  
15 accomplish the disconnection.

The cartridge vial portion of the invention includes a hollow injection/aspiration needle attached to one piston with its external pointed end initially disposed within a sealed end cap for sanitary purposes. A second  
20 piston is also provided in the cylindrical bore to operate in conjunction with the first piston to impel the injection needle and the injection fluid into the subject and then withdraw the injection needle and first piston from the subject through the sealed end cap sufficiently  
25 so that the point of the needle need not be exposed to the atmosphere before, during, or after operation of the invention. The present invention provides a means for withdrawing the needle tip into a disposable cartridge immediately after the injection and before the injector  
30 device is withdrawn from contact with the subject. This reduces the risk of unintentional exposure to a used needle tip by both users and non-users because the needle tip need never be exposed.

The programmable automatic injector portion of the  
35 invention includes a chamber for insertion of a vial, a piston operating plunger for operation of the vial, and a power source for operating the plunger. The injector

-17-

also includes a controller for varying the rate of needle insertion and withdrawal and the rate of fluid injection. The invention can be used to aspirate blood or other fluids.

#### 5 Cartridge Vial Embodiments:

The advantages and characteristics of the cartridge vial and injection/aspiration device according to the present invention can be elucidated from the following detailed description of one embodiment of the  
10 injection/aspiration device and three embodiments of the cartridge vial, to be taken as examples and not as limitations in conjunction with the accompanying drawings.

With reference to Fig. 3, a cartridge vial comprises  
15 a double-ended circularly cylindrical housing 1 constructed of rigid material and having a cartridge/ampule position locking solenoid shaft aperture 53, aspirated fluid sensor apertures 42, an ampule residence chamber 15, and cylindrical needle housing  
20 assembly receiving chamber 11. Cartridge housing 1 is provided with a puncturable sealing end cap 3 of resilient material, a plastic needle guide 5 rigidly embedded in the end cap 3 and having needle guide aperture 7 formed therein and an injection device  
25 positioning projection 9. The needle assembly receiving chamber 11 is further provided with curved abutments 13 of appropriate configuration to allow the needle assembly housing 16 to both enter and withdraw from needle assembly housing receiving chamber 11. Needle assembly  
30 housing 16 and ampule 31 are both initially disposed within ampule residence chamber 15. A glass ampule 31, positioned within the cartridge, is provided with a three portion chamber in which is stored a fluid charge 51. The first portion 33 of ampule 31 freely communicates  
35 with second portion 35 and third portion 37. Third

portion 37 is provided with a puncturable ampule stopper 39 of a resilient material. An ampule piston chamber abutment 40 forms the transition between first ampule portion 33 and second ampule portion 35 and forms a stop for a piston 45 during operation of the invention. The external portion of the transition between first ampule portion 33 and second ampule portion 35 forms an ampule shoulder 41. Ampule 31 is further provided with flange engaging lips 43 which are formed by the narrowing transition area between second chamber portion 35 and third chamber portion 37.

Ampule 31 is further provided with a piston 45 of resilient material for reversibly engaging a pointed plunger shaft head 49 having a plunger shaft 47 of an injection/aspiration device. Such an ampule could be reversibly engaged to the injection/aspiration device by many other means, other than a piston like piston 45 as shown, such as a T-shaft and keyway or any other means providing secure reversible engagement of a cartridge device to an injection/aspiration device.

Needle assembly housing 16 is provided with a needle assembly housing bottom 18, needle housing walls 17, needle assembly housing flanges 19 and needle assembly housing lips 21 disposed for securely engaging ampule 31. Needle assembly housing 16 is further provided with a hollow injection needle 23 which passes therethrough and has an internal tip 25 disposed toward puncturable ampule stopper 39 and an external tip 27 which passes through aperture 7 of needle guide 5 but does not protrude through sealing end cap 3.

Needle assembly housing walls 17 are of sufficient length so that, in operation of the cartridge as described hereinbelow, third ampule portion 37 is captured by the engagement of needle assembly housing flange lips 21 by flange engaging step 43 of ampule 31 before needle internal end 25 contacts puncturable ampule end stopper 39 and when ampule 31 has been

-19-

propelled a sufficient distance toward puncturable cartridge sealing end cap 3 that needle assembly housing 16 is fully within needle assembly housing receiving chamber 11.

5           Although a bar code indicator is seen as an efficient means for labeling both the cartridge vial and injector/aspirator components of the invention, any other means or multiple means could be employed to label the invention for machine readable purposes and for human  
10       readable purposes. For instance, both components of the invention could be labeled concurrently with readable magnetic strips, braille bumps and alphanumeric symbols.

          The above-described embodiment of the ampule type cartridge vial of the invention operates as described  
15       hereinbelow.

          Piston 45 is propelled toward sealable end cap 3 by the application of force to plunger shaft 47 which force is communicated through plunger shaft head 49 to piston 45 thus applying hydraulic pressure through fluid charge  
20       51 and forcing ampule 31 onto needle assembly 16. Continued pressure on plunger shaft head 47 is communicated through needle housing flanges 19 needle housing walls 17 and needle housing bottom 16 to needle 23, thus propelling needle 23 through needle guide  
25       aperture 7 causing external needle tip 27 to puncture puncturable end cap 3. Continued force toward puncturable cartridge sealing end cap 3 by piston 45 continues to propel needle 23 outward until needle housing 16 is stopped by sealable end cap 3, thus  
30       positioning needle assembly housing 16 within needle assembly receiving chamber 11 which is of a larger diameter than ampule residence chamber 15. The positioning of needle assembly 16 within the needle assembly receiving chamber allows flanges 19 and walls 17  
35       of needle assembly 16 to expand to irreversibly and securely receive and capture the third portion 37 of ampule 31. Continued pressure in the same direction

causes puncturable ampule stopper 39 on ampule 31 to be driven into internal needle tip 25 thus puncturing ampule stopper 39 and causing ampule stopper 39 to contact needle assembly housing bottom 18. At this time in the operation of the invention, cartridge/ampule position locking solenoid 29 (shown in Fig. 1 but not shown in Fig. 3) is energized causing cartridge/ampule position locking solenoid shaft 31 (also shown in Fig. 2 but not shown in Fig. 3) to extend through cartridge/ampule position locking solenoid aperture 53 thus locking ampule 31 and needle assembly 17 tightly against needle guide 5.

The direction of force on plunger shaft head 49 may then be reversed causing a slight withdrawal of piston 45 away from end cap 3, thus causing aspiration into fluid 51 in ampule 31 of physio-logical fluid(s) if needle tip 27, now located at a possible injection site in tissue, is in communication with such fluid. An aspirated fluid sensor 233 and light source, such as a photodiode or photocell 232 in the injection/aspiration component of the invention (shown in Fig. 1 but not in Fig. 3), then scan the fluid in ampule 31 through aspirated fluid sensor apertures 42 to spectrophotometrically detect the presence of physiological fluid(s).

If no fluids are detected and it is regarded as desirable or appropriate that none be aspiratable from an injection site for the drug being administered, or if fluid(s) that are detected do not indicate that the possible injection site, at which needle tip 27 is located is undesirable or inappropriate, the injection cycle continues and the site at which needle tip 27 is located, is employed as the injection site. Continued force in the same direction toward end cap 3 on piston 45 causes the expulsion of fluid charge 51 through needle 23 into the subject. In operation of the invention, with respect to an automatic injection/aspiration device of the type discussed above, the rate of propulsion of piston shaft head 49 is varied to control the rate of

-21-

insertion of needle 23 and the rate of injection of fluid charge 51. Also in the operation of the invention, a typical time for this sequence of inserting hollow injection needle 23 is on the order of 100 milliseconds.

5 After the injection of fluid charge 51 the operational sequence is continued into the retraction/needle capture stage by the reversal of force on piston shaft head 49 thus causing pressure on piston 45 to be directed away from sealing cap 3. The partial vacuum created by the

10 withdrawal of piston 45 causes ampule 31 to retract from needle 23 a sufficient distance so that internal needle tip 25 no longer penetrates puncturable ampule end stopper 39. The retraction of ampule 31 from needle tip

15 between curved needle assembly housing flanges 19 and curved ampule shoulders 41. Thus, needle assembly housing flanges 21 are then engaged to flange engaging steps 43 on ampule 31. Locking solenoid shaft 231 (shown in Figure 1 but not in Figure 3) is then withdrawn allowing

20 further retention of the connected ampule/needle assembly. The ampule and needle assembly, thus irreversibly engaged, is withdrawn as piston 45 is withdrawn by continued force in the direction away from puncturable sealing end cap 3 thus withdrawing needle 23

25 from the injection site a sufficient distance so that external needle tip 27 is captured completely within needle assembly receiving chamber 11. Thus, no part of needle 23 need ever be exposed to any environment other than the subject's tissues or the inside of the cartridge

30 vial. A typical time for operation of the withdrawal/needle capture sequence is on the order of 200 milliseconds.

During operation of the invention, if an undesirable or inappropriate physiological fluid (e.g. blood) or lack

35 of physiological fluid (e.g., lack of blood if an intravenous injection is intended) is detected by aspirated fluid sensor 233, the injection sequence may be

automatically stopped, thus preventing the injection of medicine or other fluids into an undesirable or inappropriate injection site.

5 With reference to Figure 4, an embodiment of the cartridge vial of the present invention intended for injections where no aspiration is necessary is illustrated. Cartridge 401 is provided with slidable ampule 431 having piston 445 for the receipt of a barbed plunger shaft head known in the dental injection  
10 cartridge field and having a second ampule portion 435 which is smaller than third ampule portion 437 the transition area therebetween forming an engaging surface for engaging flanges 419 of needle housing assembly 418. Needle assembly housing 418 is provided with needle  
15 assembly housing walls 417 of sufficient length that when the flanges capture third portion 437 of ampule 431 needle tip 425 has already punctured puncturable ampule end stopper 439. It can thus clearly be seen that the retraction of needle assembly housing 418 and needle 423  
20 are accomplished without permitting the withdrawal of needle tip 425 from puncturable end cap 439.

The additional advantages and characteristics of a non-ampule type embodiment according to the present invention can also be elucidated from the following  
25 detailed description of a second embodiment of the cartridge vial component, to be taken as an example and not as a limitation in conjunction with the accompanying drawings.

The cartridge type vial illustrated in Fig. 2  
30 comprises: a double-ended circularly cylindrical glass tube 101 provided with a puncturable sealing end cap 103 of resilient material, a rigid plastic needle guide 105 rigidly embedded in the puncturable end cap, and a first piston 117 slidably seated within the bore 118 of the  
35 cartridge. First piston 117 is provided with an operating rod engagement shaft 119 having shaft end 120. The cartridge also comprises a second piston 115 which is

also slidably disposed within the bore 118 of the cartridge. An internal end 111 of hollow injection needle 107 passing through piston 115 and is rigidly attached thereto by a needle anchoring washer 113.

5 Hollow injection needle 107 also has an external end 109 which extends through a cylindrical aperture 104 in needle guide 105 so that tip 109 at the external end does not pass through puncturable end cap 103. Cylindrical aperture 104 is of sufficient diameter to allow the

10 expulsion of air from chamber 125 during operation of the device. Second piston 115 is also rigidly fitted with a stainless steel engaging barb 121 which extends toward first piston 117. Medicinal fluid charge 123 is disposed between piston 117 and piston 115.

15 The cartridge vial of the invention operates as described hereinbelow.

The space in bore 118 between piston 117 and piston 115 is filled with a charge of fluid medicine 123 to be injected into a subject. Piston 117 is propelled by

20 means of a rigidly connected piston rod 119 toward piston 115 forcing piston 117 toward piston 115 thus applying hydraulic pressure through fluid charge 123 to piston 115 which forces piston 115 longitudinally through the bore 118 of the cartridge. This in turn drives hollow

25 injection needle 107 which is guided by needle guide 104 through puncturable end cap 103. Continued pressure on piston shaft head 120 communicated through piston shaft 119 drives piston 115 onto needle guide 104 which stops piston 115. Cartridge/ampule position locking solenoid

30 229 (not shown in Fig. 2, see Fig. 1) is then operated to insert solenoid shaft 231 (not shown in Fig. 2, see Fig. 1) thus locking cylinder 101 against end cap 103.

The direction of force on piston plunger shaft head 120 may then be reversed to cause a slight withdrawal of

35 piston 117 away from end cap 103 thus causing aspiration of physiological fluid(s), into fluid charge 123, if needle tip 109, now located at a possible injection site

in tissue, is in communication with such fluid. Aspirated fluid sensor 233 and light source (photodiode or photocell 232) (shown in Fig. 1 but not in Fig. 2) in the injection/aspiration component of the invention  
5 (shown in Fig. 2 but not in Fig. 1) then scans the fluid in the bore between piston 117 and piston 118 to detect the presence of physiological fluid(s). If no fluids are detected and it is regarded as desirable or appropriate that none be aspiratable at the possible injection site  
10 at which needle tip 109 is located, or if the fluid(s) that are detected do not indicate that the possible injection site is undesirable or inappropriate, the injection cycle continues with the possible site used as the actual injection site or injection of the medicinal  
15 charge.

Continued force on piston 117 through piston shaft 119 then causes expulsion of the medicinal fluid charge 123 through hollow injection needle 107 and into the subject. Continued force on piston shaft 119 impels  
20 piston 117 to be within a predetermined distance from piston 115 sufficiently onto barb 121 to irreversibly lock needle 107 and piston 117 to piston 115 as a last portion of medicinal fluid charge 123 is expelled from the bore. Locking solenoid shaft 231 (not shown in Fig.  
25 2, see Fig. 1) is then withdrawn allowing withdrawal of the cartridge. When the direction of the force on piston shaft 119 is reversed, piston 117 withdraws away from end cap 103 through the cartridge bore drawing piston 115 which has been locked to piston 117 by means of stainless  
30 steel locking barb 121 away from needle guide 104 thus withdrawing needle 107 which is rigidly attached by anchor washer 113 to piston 115. Continued force in this withdrawal direction on piston 119 withdraws point 109 of needle 107 through puncturable end cap 103 and needle  
35 guide 104 so that needle end 109 is captured within the cylindrical bore of the cartridge, thus the entirety of

needle 107 is disposed completely within bore 118 of the cartridge after the injection cycle is completed.

During operation of this embodiment, if an undesirable or inappropriate physiological fluid (e.g. blood) or lack of physiological fluid (e.g., lack of blood if an intravenous injection is intended) is detected by aspirated fluid sensor 233 the injection sequence is automatically stopped, thus preventing the injection of medicine or other fluids into an undesirable or inappropriate injection site.

Although one preferred method of using the cartridge vials of the types described above is with a powered automatic injection/aspiration device also as described above, it can be clearly seen that a mechanically or manually powered injection device is preferable to operate such cartridge vials in some circumstances. For instance, where batteries or electrical power are unavailable or undesirable due to storage problems or where there is a need for a more compact, more simple, or less expensive device, a mechanical injector is preferred. Moreover, it is desirable to have an injector of which all the components can be stored for long periods of time, and which are suitable for sterilization by gamma or other radiation, electron beams, or gases such as ethylene oxide. Figures 5-8 illustrate a preferred embodiment of a mechanical actuator and cartridge according to the invention.

With reference to Figure 5, an embodiment of the cartridge vial of the present invention intended for injections where no aspiration is necessary is illustrated. Cartridge 2401 is provided with slidable ampule 2431 having piston 2445 for expelling fluid from fluid chamber 2438 and having a second ampule portion 2435 which is smaller in outer diameter than third ampule portion 2437, the transition area therebetween forming an engaging surface 2436 for engaging flanges 2419 of needle housing assembly 2418. Needle assembly housing 2418 is

provided with needle assembly housing walls 2417 of sufficient length that when the flanges 2419 capture third portion 2437 of ampule 2431 needle tip 2425 has already punctured puncturable ampule end stopper 2439.

5 Needle housing assembly walls 2417 are of a sufficient diameter such that expansion of walls 2417 cannot occur until needle housing assembly 2418 is pushed into needle housing assembly residence chamber 2411 by the movement of slidable ampule 2431.

10 With reference to Figures 6 and 7, an embodiment of a cartridge vial actuator of the present invention intended for injections is illustrated. Cartridge vial actuator housing 2001 is provided with cartridge vial receiving chamber 2005 for receiving a cartridge vial of the type shown in Figure 5 and is also provided with  
15 cartridge vial locking indentations 2004 for engaging and positioning a cartridge vial. Cartridge vial actuator housing 2001 is also provided with cartridge vial positioning abutment 2003 for holding a cartridge vial in a predetermined position. Cartridge vial actuator  
20 housing 2001 is also provided with piston driver residence chamber 2006 wherein piston driver 2007 is slidably seated.

Piston driver 2007 is releasably attached through  
25 piston driver flange seat 2019 in the body of housing 2001 by piston driver release flanges 2017 which are attached to piston driver release arms 2015. Piston driver 2007 is also provided with piston driver spring 2013 which is coiled around piston driver release arms  
30 2015 in a compressed condition and abutting on piston driver spring shoulder 2009 and housing spring shelf 2016 thus biasing piston driver 2007 toward cartridge vial receiving chamber 2005.

Cartridge vial actuator housing 2001 is also provided  
35 with firing cap 2021 having flange constriction surfaces 2035 which loosely abut piston driver release flanges 2017. Firing cap 2021 is also provided with firing cap

attachment lip 2023 which surrounds firing cap engagement ring 2018 and is further provided with firing cap slot 2025 which permits the longitudinal movement of firing cap 2021 with respect to cartridge vial actuator housing 2001. Firing cap 2021 is also provided with firing cap safety pin aperture 2027 for receiving safety pin/needle cover 2031 therethrough.

It can thus be clearly seen that piston driver release arms 2015 and piston driver flanges 2017 are held seated on piston driver flange seat 2019 by the expansion of piston driver safety pin void 2029 by safety pin/needle cover 2031. Safety pin/needle cover 2031 is also provided with needle cover aperture 2033 which can be used to cover the protruding portion of injection needle 2423 after an injection, e.g. injection needle 2423 shown in Figure 5. See Figure 8.

The mechanically actuated cartridge vial of the invention, as shown in figures 5-8, operates as described hereinbelow.

The space in ampule fluid chamber 2438 is filled with charge 2440 of fluid medicament to be injected into a subject. Cartridge vial housing 2401 is disposed within cartridge vial receiving chamber 2005 of cartridge vial actuator housing 2001 in a position determined by cartridge vial position abutment 2003 and cartridge vial locking indentations 2004 and cartridge vial locking projections 2434.

The force of compressed piston driver spring 2013 is released by the following actions: safety pin/needle cover 2031 disposed within piston driver safety pin void 2029 is withdrawn from void 2029 through firing cap safety pin aperture 2027. Firing cap 2021 is then depressed in the direction of cartridge vial receiving chamber 2005 thus causing angled flange constriction surfaces 2035 to impinge upon the angled surfaces of piston driver release flanges 2017 thereby causing the movement of those flanges toward each other and

-28-

permitting flanges 2017 to be pulled through an aperture in piston driver flange seat 2019 by the force of expanding piston driver spring 2013 thus causing movement of piston driver 2007 in the direction of cartridge vial end cap 2403. The movement of piston driver 2007 causes cartridge vial piston contact face 2011 to contact piston 2445 disposed above fluid chamber 2438 in ampule 2431 thus applying hydraulic pressure through fluid charge 2440 to propel slidable ampule 2431 toward end cap 2403.

Thus, continued movement of piston driver 2007 causes movement of needle assembly housing 2418 also in the direction of end cap 2403 so that injection needle 2423 punctures end cap 2403 and needle assembly housing 2418 enters needle assembly housing residence chamber 2411 until the needle assembly housing is stopped by needle guide 2404 disposed within end cap 2403. Continued pressure on piston 2445 then causes the expansion of needle assembly housing flanges 2419 and the puncture of puncturable ampule end stopper 2439 by needle internal end 2425.

Continued pressure on piston 2445 by expanding piston driver 2013 communicated through piston driver 2007 causes ejection of fluid charge 2440 through hollow injection needle 2423 until piston 2445 bottoms out against ampule internal abutment 2432. The mechanically actuated cartridge vial is then removed from a subject target area and safety pin/needle cover 2031 is then placed over the exposed portion of extended injection needle 2423 to prevent unwanted or unintentional punctures by the needle. Thus, no part of needle 2423 need ever be exposed to any environment other than the subject's tissues or the inside of the cartridge vial before injection.

A preferred material for the actuator housing, cartridge housing, needle assembly housing, firing cap, needle guide, end cap, safety pin/needle cover, and piston driver is radiation resistant polypropylene known

in the medical arts. However, it can clearly be seen that many other materials which are standard in the medical and dental packaging and hypodermic syringe art such as plastics, including glass-filled plastics, carbon  
5 fiber composites, rubber, synthetic and nonsynthetic materials known in the art and nylon/carbon fiber composites. A preferred material for the injection needle and piston driver flange seat is stainless steel. However, any other reasonable substitute material such as  
10 glass, ceramics, and carbon fiber composites are acceptable.

Similarly, a preferred material for the piston driver is a nylon/carbon fiber composite, although numerous other materials having sufficient resilience, rigidity,  
15 and tensile strengths are acceptable to practice the present invention.

Preferred materials for the ampule piston, cartridge end cap, and puncturable shield include natural or synthetic rubber, silicone rubber, glass-filled silicone  
20 rubber, and various plastics so long as the desired characteristics of sealability, puncturability, and manufacture to precise tolerances are achievable. A preferred material for the puncturable ampule end stopper is a rubber disk or membrane securely attached and sealed  
25 to the ampule by an aluminum cover as is standard in the medical and dental arts.

A preferred material for the ampule is silicone treated USP glass, although many plastics and composite materials are also suitable as known in the art.

30 Suitable materials for the piston driver spring also include carbon steel, stainless steel, glass-filled nylon, various glasses, or any other material capable of providing biasing and propelling force in the context of the invention.

35 It is preferred that all components of the invention be amenable to sterilization by processes using gamma rays, electron beams, or ethylene oxide. Such materials

include ABS plastics, polycarbonates, glasses and carbon fiber composites.

5 The needle assembly housing dimensions must be tailored with respect to the specific material used in order to achieve acceptable deformation characteristics to permit expansion of the needle assembly housing flanges under the particular amount of force transmitted from the piston driver spring. Of course, it can also be clearly seen that spring characteristics such as  
10 uncompressed length, material, and stiffness can be varied to adapt the piston driver spring for use with particular types of ampule and needle housing assemblies.

With slight modifications, the present invention can be adapted to be driven by forces other than the release  
15 of a compressed spring. For example, a device of the invention can be driven by release of a compressed gas releasably contained in a receptacle substituted for the piston driver arms 2015 and spring 2013 as shown in Figures 6 and 7. Release of the gas would then drive  
20 piston 2445 toward end cap 2403 of cartridge vial housing 2401 seated in receiving chamber 2005 to thus operate the invention in a manner similar to that of the spring-actuated cartridge described above.

Of course, it is also clear that, with slight  
25 modification of the present invention, the device can be configured to permit retraction of the needle, after injection, to reside wholly within the cartridge vial.

In a further adaptation, some portion of the trigger end of piston driver 2007 could be made frangible to the  
30 action of the detent release. For example, driver flanges 2017 could be made of a brittle plastic or composite which, upon depresssion of firing cap 2031, break away from release arms 2015 to release the energy of spring 2013. Thus, the device can be made to be non-  
35 reusable to prevent unsanitary or unwanted use. Examples of materials of which the frangible component can be made include glass-filled composites, metal-filled composites,

carbon fiber composites, fiberglass, glasses, nylon, nylon/carbon fiber composites, and wood.

5 For example, by providing barbs or other means for irreversibly engaging the ampule piston to the piston driver, and by providing means whereby the actuator assembly can be disengaged from the cartridge vial in a manner which allows withdrawal of the piston driver from the ampule, retraction of the injection needle to reside wholly within the cartridge can be accomplished.

10 It can also be clearly seen that both the injector and the injector/aspirator of the present invention are suitable for use with cartridges of the type disclosed in related application Serial No. 07/740,843, filed August 6, 1991. Suitable modifications in the chamber for receipt of a cartridge may be necessary in order to adapt the present devices for use with some of the two-component cartridges disclosed in the '843 application. However, these modifications are seen to be within the scope of the present invention and can be readily carried out by the skilled in the art. These cartridges are adapted for the storage of two components, at least one of which is a fluid, to form a fluid, injectable medicament immediately prior to injection and require a force applied to a piston for actuation.

25 With reference to the resilient materials disclosed herein, such materials are those standard in the medical and dental packaging and hypodermic syringe art such as rubber, plastics, and other synthetic and non-synthetic materials known in the art for accomplishing similar and related objectives. Also, all of the embodiments of the cartridge vials disclosed herein are adapted to be manufactured by standard medical and dental ampule and container manufacturing equipment.

30 Similarly, the cartridge vials disclosed herein are adapted to contain, when fully charged, from 0.1 to 100 milliliters of fluid. However, more typically such vials

-32-

will contain, when fully charged, from 0.5 to 10 milliliters of fluid.

The needles will have lengths and gauges, and will be made of materials, that are standard in the hypodermic  
5 syringe/needle art.

-33-

CLAIMS:

1. A mechanically actuated fluid injector device comprising:

(A) a tubular cartridge, having a first end and a second end, said cartridge having, an interior bore which is widened at said second end of said cartridge to form a needle housing assembly residence chamber for reversibly receiving a needle housing assembly, and a puncturable end cap, said end cap sealing said second end of said cartridge;

(B) an ampule disposed within said cartridge bore having a first portion and a second portion, said ampule being suitable for storing a fluid charge to be expelled therefrom;

(C) a piston slidably seated within said first portion of said ampule;

(D) a puncturable ampule end stopper rigidly attached to and sealing said second portion of said ampule;

(E) a needle housing assembly disposed in said cylindrical bore of said cartridge said needle housing assembly comprising

a housing,

a hollow injection needle rigidly attached to said housing and having an internal end and an external end, said internal end of said needle extending through said needle housing assembly toward said puncturable ampule end stopper, and said external end of said hollow injection needle extending toward said puncturable end cap of said cartridge without protruding therefrom; and

(F) an actuator engageable with said tubular cartridge for propelling said ampule toward said needle housing assembly and said puncturable end cap and for propelling said piston within said ampule toward said ampule end stopper to inject said fluid charge through said hollow injection needle.

-34-

2. A device as recited in claim 1, where said needle housing assembly is provided with locking means for irreversibly locking said needle assembly housing to said ampule when said needle housing assembly and said ampule are a predetermined distance apart.

3. A device as recited in claim 1, wherein said actuator (F) comprises:

(i) an actuator housing, said housing having a first end and a second end, said first end adapted for receiving said tubular cartridge and said second end adapted for operating said actuator;

(ii) a piston driver slidably seated in said housing, said driver having a piston face for contracting said ampule piston, a transfer surface for transferring propelling force from said housing to said driver, and a trigger end for releasably engaging said second end of said actuator housing;

(iii) a detent in said second firing end for releasably engaging said piston driver;

(iv) a detent release in said second firing end for disengaging said piston driver from said second end;

(v) a propulsion mechanism disposed between said transfer surface and said second end of said housing for driving said piston driver toward said puncturable end cap when said detent release is triggered.

4. A device as recited in claim 3, wherein said propulsion mechanism is a spring.

5. A device as recited in claim 4, wherein said spring comprises one or more materials from the group consisting of metals, glasses, composites and plastics.

-35-

6. A device as recited in claim 3, wherein said propulsion mechanism is a compressed gas releasably contained in a receptacle.

5 7. A device as recited in claim 1, further comprising a readable indicator.

8. A device as recited in claim 1, further comprising locking means for preventing unintentional  
10 discharge of said device.

9. A device as recited in claim 8, wherein said locking means comprises a removable pin having a projection for preventing activation of said detent  
15 release.

10. A device as recited in claim 9, wherein said locking means further comprises a recess of suitable dimension for covering and gripping said needle portion protruding from said puncturable end cap after an  
20 injection.

11. A device as recited in claim 1, further comprising a readable indicator for matching cartridge  
25 vials and ampules to said actuator and for indicating patient information.

12. A device as recited in claim 3, wherein said trigger end of said piston driver comprises a shaft  
30 frangible to the action of said detent release.

13. A device as recited in claim 12, wherein said frangible shaft comprises one or more materials from the group comprising glass-filled composites, metal-  
35 filled composites, carbon fiber composites, fiberglass, glass, nylon, nylon/carbon fiber composites, and wood.

-36-

14. A device as recited in claim 1, wherein said external end of said injection needle is disposed within said puncturable end cap of said cartridge a sufficient distance to provide a microbe-impermeable seal without protruding therefrom.

15. A device as recited in claim 1, wherein said internal end of said injection needle is disposed within a puncturable shield a sufficient distance to provide a microbe-impermeable seal without protruding therefrom.

16. A device as recited in claim 15, wherein said puncturable end cap of said cartridge is provided with one or more compounds from the group comprising antiseptics, antibiotics, antivirals and antimicrobials.

17. A device as recited in claim 15, wherein said puncturable shield is provided with one or more compounds from the group comprising antiseptics, antibiotics, antivirals and antimicrobials.

18. A method of administering fluid medication, comprising:

(A) providing a cartridge, having a first end and a second end, said cartridge comprising:

(i) a cylindrical bore which is widened at said second end of said cartridge to form a cylindrical needle housing assembly residence chamber for receiving a needle housing assembly, and

(ii) a puncturable end cap, said end cap sealing said second end of said cartridge;

(iii) an ampule disposed within said cartridge bore having a first portion and a second portion, said ampule being suitable for storing a fluid charge to be expelled therefrom;

-37-

(iv) a piston within said first portion of said ampule and being slidably seated in said ampule;

(v) a puncturable ampule end stopper rigidly attached to and sealing said second portion of  
5 said ampule;

(vi) a needle housing assembly disposed in said cylindrical bore of said cartridge said needle housing assembly comprising

a housing,

10 a hollow injection needle rigidly attached to said housing and having an internal end and an external end, said internal end of said needle extending through said needle housing assembly toward said puncturable  
15 injection needle extending toward said puncturable end cap of said cartridge without protruding therefrom; and

(vii) an actuator for engaging said cartridge vial and for propelling said ampule toward said puncturable end cap and for propelling said piston within  
20 said ampule toward said ampule end stopper to inject a fluid;

(B) placing said cartridge end cap on an injection site;

(C) triggering said actuator;

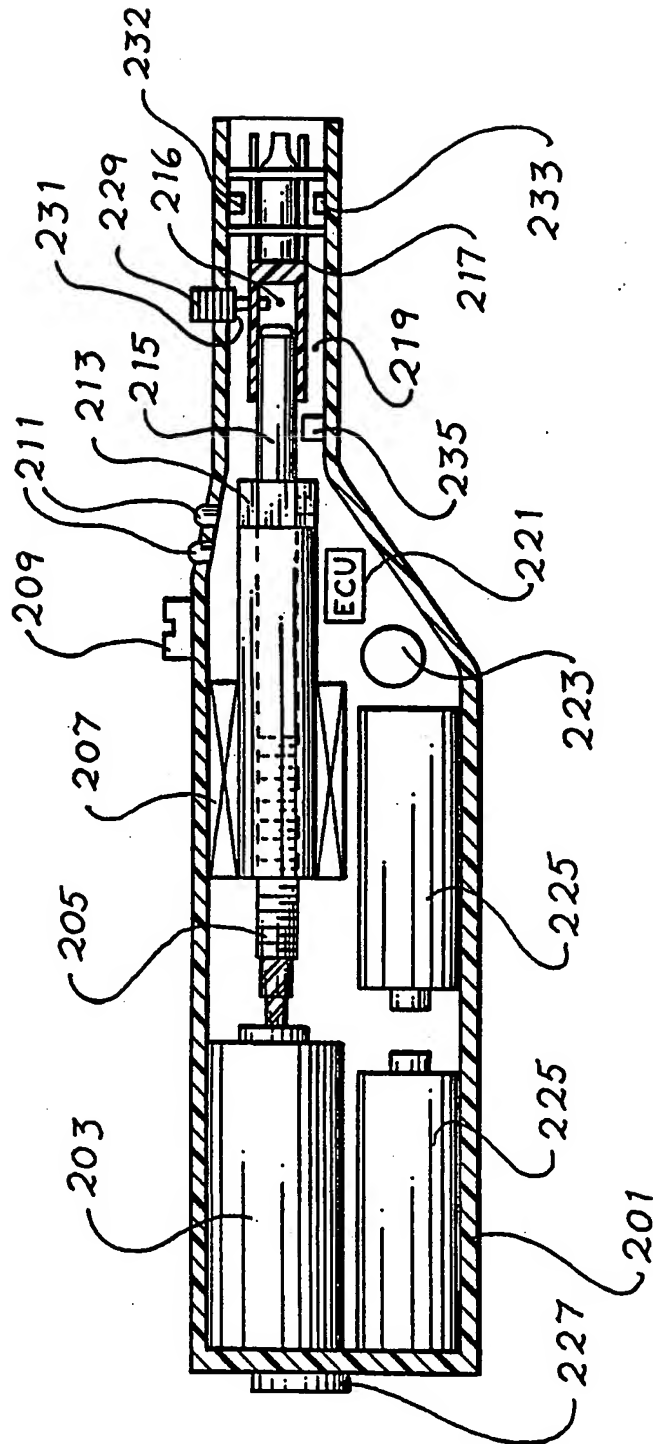
25 (D) maintaining said contact with said injection site until said fluid is injected;

(E) withdrawing said device from said injection site.

30 19. The method of claim 18, further comprising:

(F) covering, after an injection, the needle portion protruding from said puncturable end cap with said actuator locking means.

35



**FIG. 1**

2/8

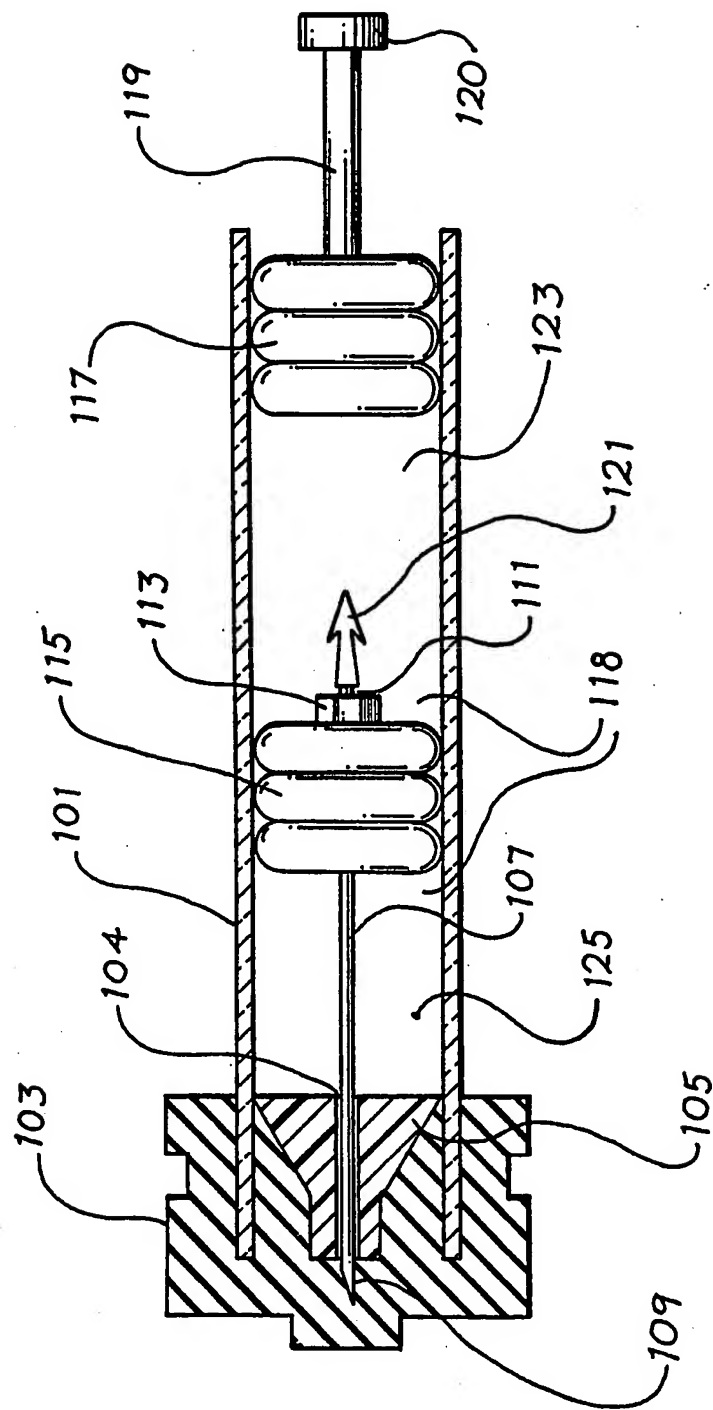


FIG. 2

3/8

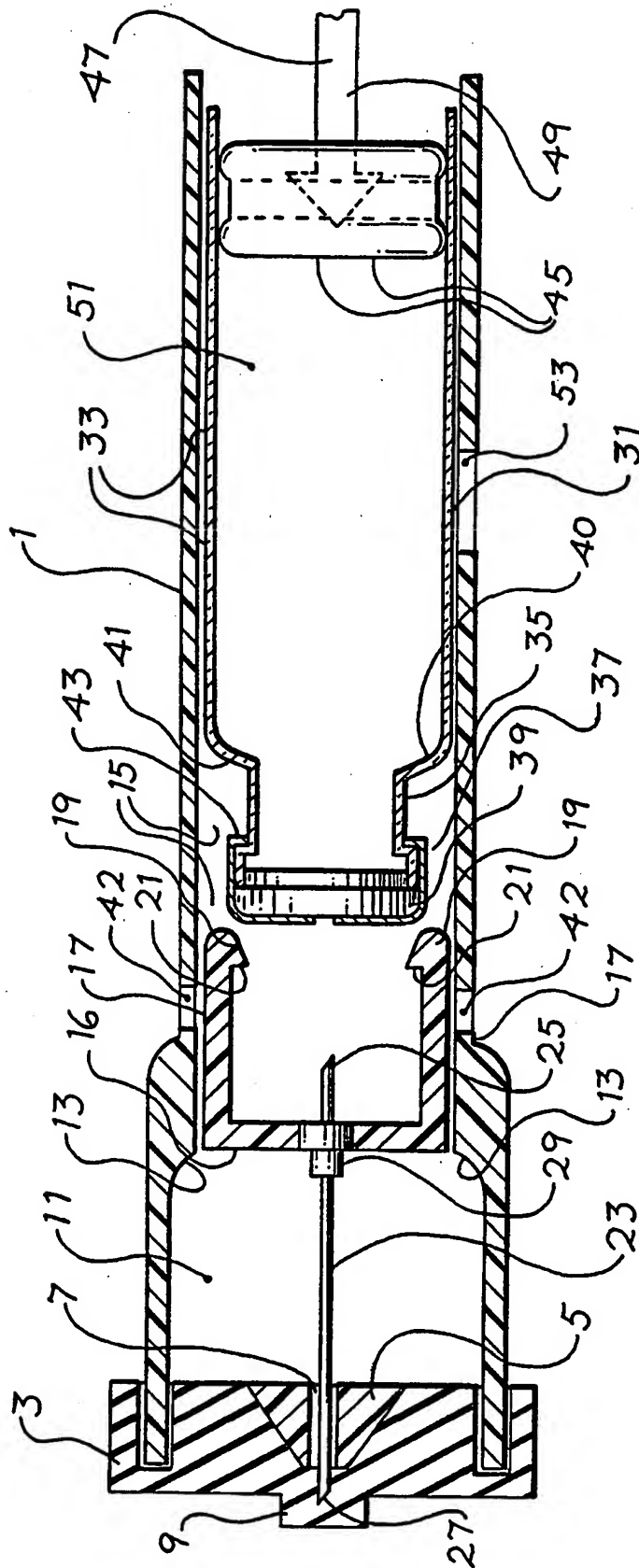


FIG. 3

4/8

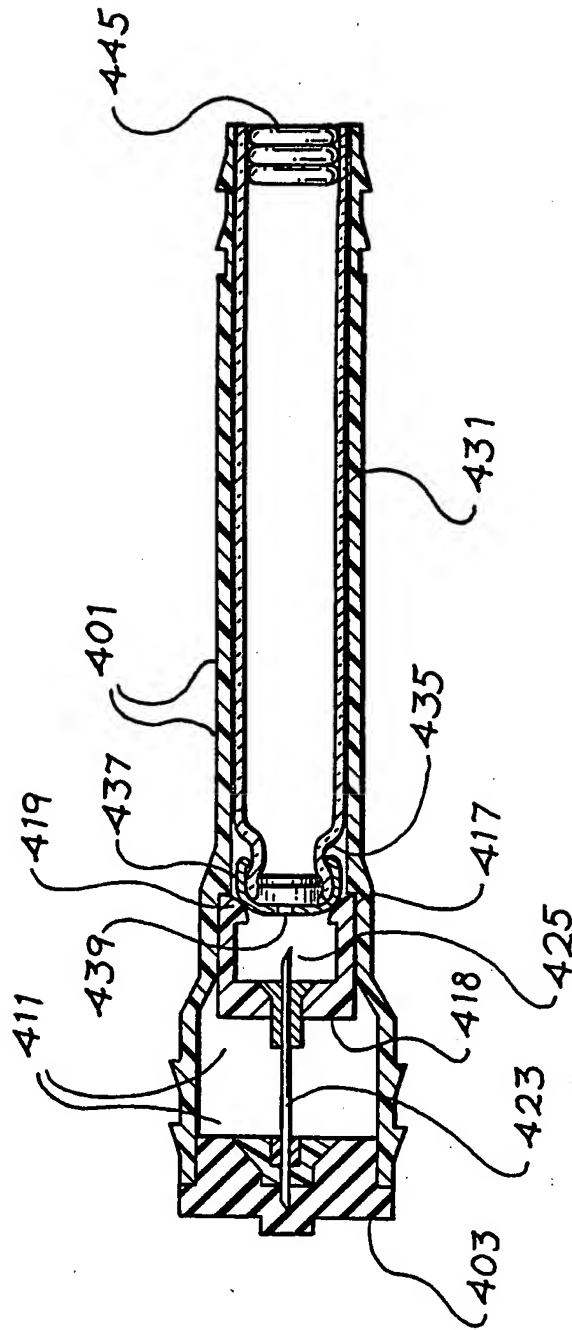


FIG. 4

5/8

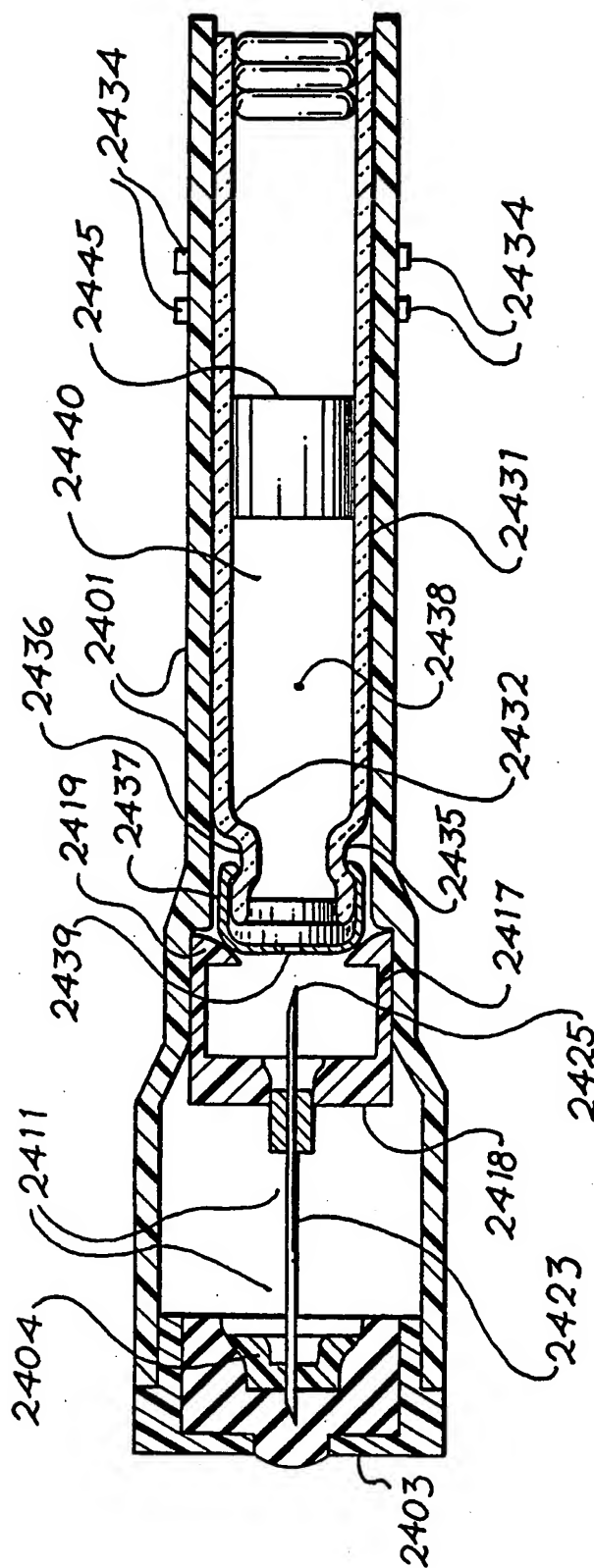
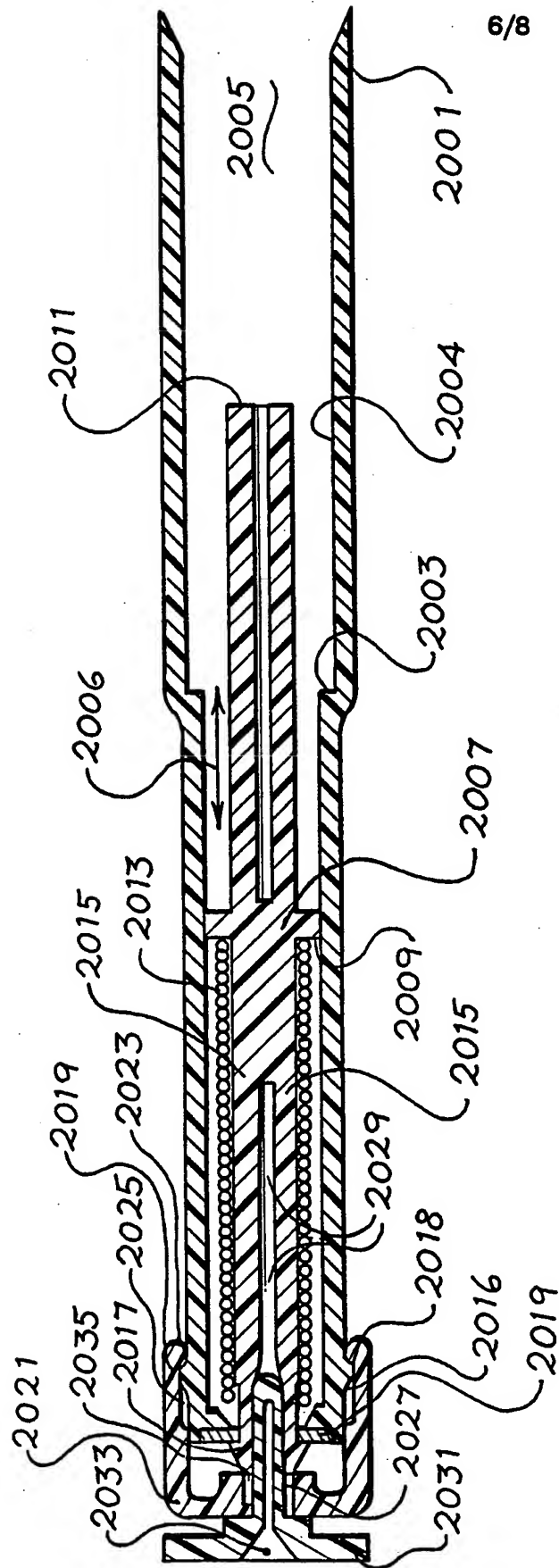
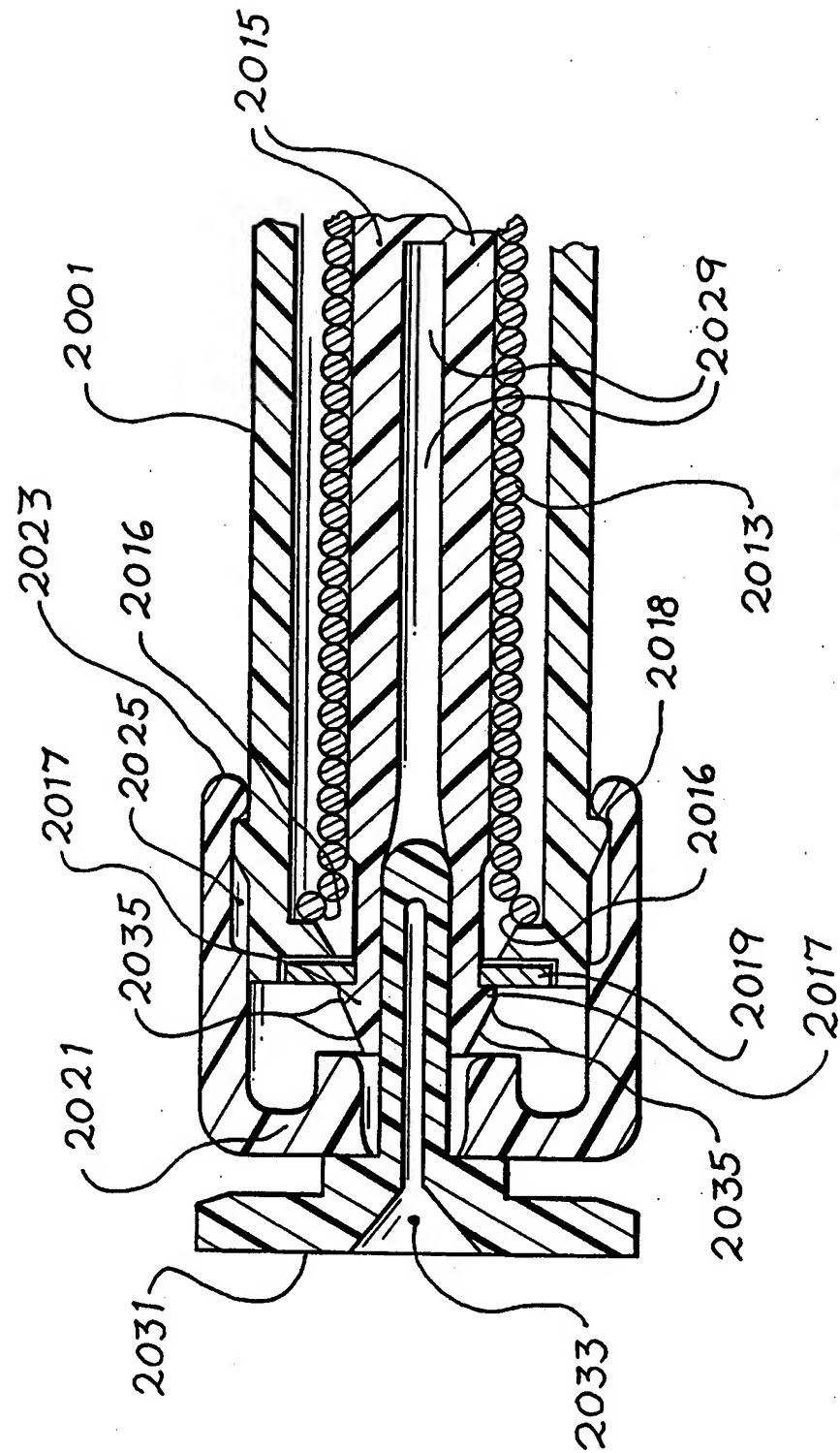


FIG. 5



**FIG. 6**



**FIG. 7**

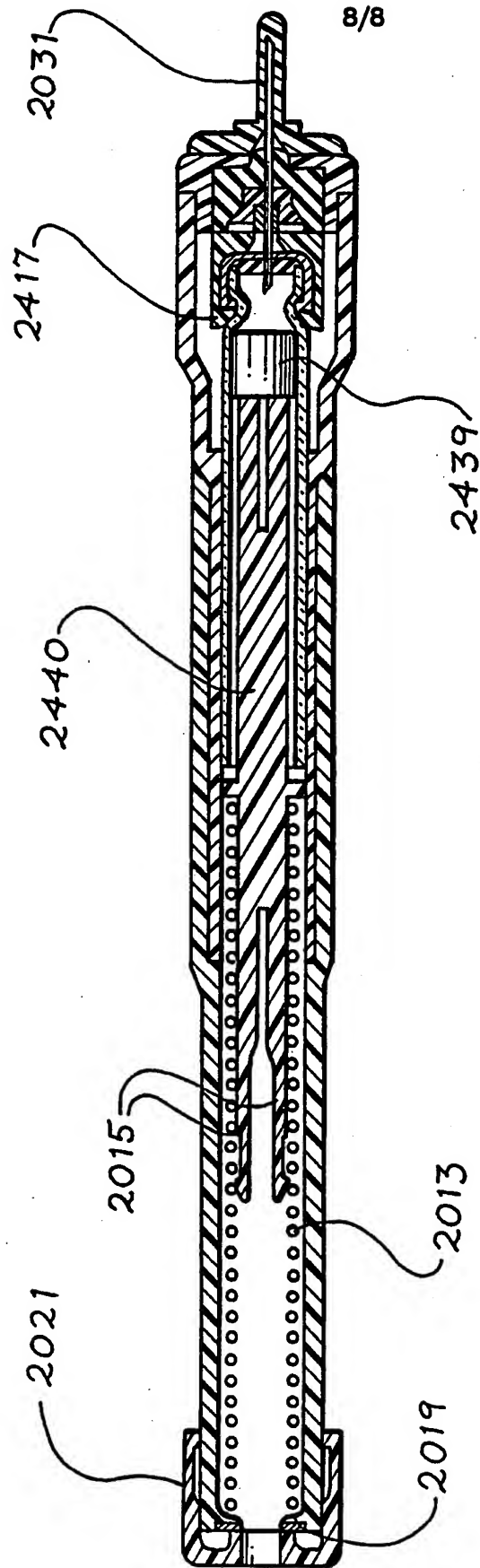


FIG. 8

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US93/09376

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 5/20, 37/00, 5/178, 5/00

US CL :604/135, 139, 141, 144, 186, 232

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : Please See Extra Sheet.

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, , 5,102,393, (Sarnoff et al.) 07 April 1992. See Fig. 1.	1-5, 7-9, 11, 16
X	US, A, 4,394,863 (Bartner) 26 July 1983. See entire document..	1-5, 7-9, 11, 18
X	US, A, 3,742,948 (Post et al.) 03 July 1973. See entire document.	1-5, 7-9, 11, 18
X	US, A, 3,702,609 (Steiner) 14 November 1972. See entire document.	1, 3-5, 7-9, 11, 15, 18
X	US, A, 3,182,660 (Weydanz et al.) 11 May 1965. See entire document.	1, 3-5, 7, 8, 11-15, 18
X	US, A, 3,136,313 (Enström et al.), 09 June 9, 1964. See entire document.	1-5, 7, 8, 11-15, 18

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be part of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

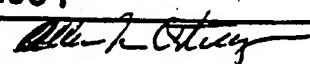
Date of the actual completion of the international search

28 December 1993

Date of mailing of the international search report

FEB 15 1994

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Authorized officer   
RONALD STRIGHT, JR.

Facsimile No. NOT APPLICABLE

Telephone No. (703) 308-0858

**INTERNATIONAL SEARCH REPORT**International application No.  
PCT/US93/09376**C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 3,066,670 (Stauffer) 04 December 1962. See entire document.	1-5, 7, 8, 11, 12, 13, 14, 18
X	US, A, 4,767,413 (Haber et al.) 30 August 1988. See Fig. 2.	1, 2, 7, 8, 11, 14, 15

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US93/09376

## B. FIELDS SEARCHED

Minimum documentation searched

Classification System: U.S.

604/110, 118, 121, 123, 124, 125, 130, 131, 134-141, 143-146, 148, 154, 156, 157, 181, 186, 187, 194-198, 200, 201, 207, 210, 218, 232-237, 239, 240